REMARKS

Claim 20 is the only claim remaining in the application. Previously pending claims 1-19 have been cancelled herein.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Dr. Kenneth I. Kohn, during a personal interview with the Examiner conducted on July 10, 2007. During the personal interview, the previously pending claims were discussed in view of the prior art. Generally, during the personal interview, it was noted that although the prior art discloses biopanning to identify epitope-bearing clones, the prior art is specifically searching for the best marker to be used as a diagnostic, whereas, the present invention biopans and identifies all epitope-bearing clones for use in a protein array assay for detecting early-stage cancer. The present amendment presents new independent claim 20 which clarifies this distinguishing limitation over the prior art.

Referring specifically to the outstanding Office Action, the previously pending claims were rejected under 35 USC §103(a) as being unpatentable over the primary reference Sioud, et al., in view of either Miller, et al., or Robinson, et al. In each rejection, the Sioud, et al., reference was held to teach the analysis of humoral response in patients with cancer, wherein libraries from breast cancer cell lines were biopanned and positive clones were selected. The Miller, et al., reference was cited to teach that primary arrays may be developed to emulate antigenic diversity of a cell and to use the arrays to diagnose a human or animal for a medical condition. The Robinson, et al., reference was held to provide a *prima facie* obviousness rejection on the basis that Robinson, et al., discloses high-density arrays. It was further held that the Sioud, et al., reference does not teach the use of a "microarray."

More specifically, it is undisputed that the primary reference, the Sioud, et al., reference, discloses the step of biopanning libraries for selecting phage display cDNA products recognized by a significant number of breast cancer sera as compared to sera from normal individuals. The Sioud, et al., reference concluded that "the obtained results demonstrate that phage display could be a valuable method for the identification of antigens recognized by the humoral immune system in patients with cancer." (Sioud, et al., reference, abstract).

As argued in the last filed Response by Applicants, it is admitted that it is well-known to biopan for a specific composition, as disclosed in the Sioud, et al., reference. That is, the Sioud, et al., reference discloses biopanning methods aimed at determining the presence of a single significant marker. There is no disclosure or suggestion in the Sioud, et al., reference of a method or assay that simultaneously screens for an unlimited number of markers within sera. The cited reference only teaches obtaining approximately five to ten markers. This is known in the art to be a low throughput method. This is consistent with the commonly accepted convention of determining a single marker for diagnostic purposes, such as those used for prostate cancer, breast cancer, or the like. Moreover, the methodology disclosed in the Sioud, et al., reference teaches away from the use of a large array, or more specifically, including all epitopes uncovered during biopanning related to a disease, because the primary goal, as disclosed in the first full paragraph of page 718 of the Sioud, et al., reference is to ". . . enrich for the best binders. If the selection is specific an increase in the number of positive clones is likely." The additional selections disclosed in the Sioud, et al., reference were designed to increase the specificity for finding a few highly specific markers. Thus, if the Sioud, et al., reference were combined with either the Miller, et al., or Robinson, et al., references, the combination of references would result in a microarray including very few, if not a single specific marker, with multiple samples of sera.

The present invention provides unexpected results in view of the convention of the prior art. The present invention, as set forth in independent claim 20, is characterized by identifying all epitope-bearing clones that are specific to early-stage cancer and including all epitopes identified in protein arrays for detecting early-stage cancer. This teaching goes directly against the teachings of all the cited prior art, as discussed during the personal interview. Moreover, as discussed during the personal interview, the present invention as set forth in pending claim 20 provides unexpected results by providing a broad range, yet sensitive assay, capable of detecting early-stage cancer, as supported on page 42 of the presently pending patent application. The present invention provides a method of identifying and detecting markers indicative of early-stage cancer, thereby allowing the practitioner to utilize more specific diagnostic procedures to confirm the early-stage cancer and then prescribe early-stage treatments. The prior art does not provide markers nor does it even suggest the provision of markers for such early-stage detection of cancer. Treatment of early-stage cancer is known to be significantly more effective than treatment of later-stage cancer. Hence, the present invention provides unexpected results not obtained by the prior art. That is, the present invention includes all epitopes identified in protein array assays for detecting early-stage cancer. Such unexpected results overcome a *prima facie* obviousness-type rejection as a matter of law. Hence, it is respectfully submitted that independent claim 20 is patentable over the cited prior art.

In conclusion, the application is now in condition for allowance, which allowance is respectfully requested.

Respectfully submitted,

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I hereby certify that this correspondence is being electronically filed with the United States Patent & trademark Office on the above date.

Connie Herty